



The 2009 Influenza Pandemic: An Overview

Sarah A. Lister

Specialist in Public Health and Epidemiology

C. Stephen Redhead

Specialist in Health Policy

September 10, 2009

Congressional Research Service

7-5700

www.crs.gov

R40554

Report Documentation Page				Form Approved OMB No. 0704-0188	
Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.					
1. REPORT DATE 10 SEP 2009		2. REPORT TYPE		3. DATES COVERED 00-00-2009 to 00-00-2009	
4. TITLE AND SUBTITLE The 2009 Influenza Pandemic: An Overview				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Congressional Research Service, Library of Congress, 101 Independence Ave., SE, Washington, DC, 20540-7500				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 36	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

Summary

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be an influenza pandemic, the first since 1968. WHO said that the pandemic declaration was based on the geographic spread of the new virus, not on increasing severity of the illnesses it causes. Officials now believe the outbreak began in Mexico in March, or perhaps earlier. The novel “H1N1 swine flu” was first identified in California in late April. Health officials quickly linked the new virus to many of the illnesses in Mexico. Since then, cases have been reported around the world.

On July 16, WHO said it was suspending worldwide case counts of illnesses caused by the virus, and that it no longer wanted member nations to report individual cases. WHO said that tracking in this way was no longer helpful in monitoring the pandemic, but was unnecessarily burdensome for reporting countries. In the final WHO case count of July 6, almost 100,000 cases, and more than 400 deaths, had been reported around the world, on all continents but Antarctica. Early in the outbreak, most of the cases were in North America, and then Europe and Asia. This was followed by increasing spread in countries in the Southern Hemisphere during their winter, when flu transmission is more efficient. Transmission continued at low levels in North America throughout the summer. U.S. health officials and others are preparing for a resurgence of infections in the fall, with the onset of cooler temperatures.

When the outbreak began in late April, U.S. federal agencies adopted a response posture under the overall coordination of the Secretary of Homeland Security. Among other things, officials have released antiviral drugs from the national stockpile, developed and released diagnostic tests for the H1N1 virus, and developed guidance for the clinical management of patients and the management of community and school outbreaks. The Obama Administration requested about \$9 billion in emergency supplemental appropriations to address the situation. On June 26, the President signed P.L. 111-32, the Supplemental Appropriations Act, 2009, which provided \$1.9 billion immediately, and an additional \$5.8 billion contingent upon a presidential request documenting the need for, and proposed use of, the additional funds.

U.S. health officials have procured millions of doses of pandemic flu vaccine, which is expected to become available in stages over a period of a few months, beginning in October. Plans for a voluntary nationwide vaccination campaign are underway, to be coordinated by state health officials and carried out through public clinics, private health care providers, schools, and others. The Secretary of Health and Human Services has implemented waivers of liability and an injury compensation program in the event of unforeseen vaccine safety problems. Allocation schemes have been developed to give priority for limited vaccine doses to high-risk groups.

This report first provides a synopsis of key events, actions taken, and authorities invoked by WHO, the U.S. federal government, and state and local governments. It then discusses the WHO process to determine the phase of a flu pandemic, selected activities by the Departments of Homeland Security and Health and Human Services, and selected activities by state and local authorities. Next, it lists congressional hearings held to date, and provides information about appropriations and funding for pandemic flu activities. Finally, it summarizes U.S. government pandemic flu planning documents and lists sources for additional information about the situation. This report will be continually updated to reflect unfolding events.

Contents

Synopsis	1
Key Official Actions by WHO.....	4
Determination of Influenza Pandemic Phase.....	4
International Health Regulations	6
Travel Guidance.....	7
Food Safety Guidance	7
Key U.S. Government Activities	7
Government-wide Pandemic Preparedness and Response	7
Department of Homeland Security (DHS)	9
Leadership Designation.....	9
Applicability of the Stafford Act.....	9
Customs and Border Protection (CBP) Activities.....	10
Department of Health and Human Services (HHS)	11
Determination of a Public Health Emergency	11
FDA: Emergency Use Authorizations.....	11
CDC: Travel Notices	12
CDC: Disease Surveillance	12
Vaccine Development, Licensing, and Use	13
Naming the Virus Strain	19
Key State and Local Activities.....	20
State Pandemic Preparedness and Response	20
Pandemic Preparedness and Response in Schools	21
Congressional Hearings.....	22
Senate	23
House	23
Appropriations and Funding	24
Public Health Emergency Funding Mechanisms	24
Emergency Supplemental Appropriations for FY2009	25
Prior Funding for Pandemic Flu Preparedness	26
U.S. Pandemic Influenza Preparedness Documents	28
Key Information Sources.....	30
CRS Reports and Experts	30
World Health Organization (WHO) Information.....	31
U.S. Federal Government Information.....	31
Additional Information.....	32

Figures

Figure 1. WHO Influenza Pandemic Phases.....	6
Figure 2. Proposed Timeline for H1N1 Vaccine Development, Manufacturing, and Possible Distribution and Administration.....	16

Tables

Table 1. WHO Influenza Pandemic Phases	5
Table 2. HHS Funding for Pandemic Influenza, FY2004-FY2010.....	27

Contacts

Author Contact Information	32
----------------------------------	----

Synopsis

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be a flu pandemic, the first since 1968. WHO said that the pandemic declaration was based on the geographic spread of the new virus, not on increasing severity of the illnesses it causes. Officials now believe the outbreak began in Mexico in March, or perhaps earlier. The novel “H1N1 swine flu” was first identified in California in late April. Health officials quickly linked the new virus to many of the illnesses in Mexico. Since then, cases have been reported around the world.

On July 16, WHO said it was suspending worldwide case counts of illnesses caused by the virus, and that it no longer wanted member nations to report individual cases. WHO said that tracking in this way was no longer helpful in monitoring the pandemic, but was unnecessarily burdensome for reporting countries. Early in the outbreak, most of the cases were in North America, and then Europe and Asia. This was followed by increasing spread in countries in the Southern Hemisphere during their winter, when flu transmission is more efficient. Transmission continued at low levels in North America throughout the summer. U.S. health officials and others are preparing for a resurgence of infections this fall, with the onset of cooler temperatures.

Health officials note that reported cases represented only a fraction of actual infections. For example, U.S. health officials estimated that by late June there had been more than one million infections in the United States, although there were only about 28,000 reported cases at that time. In May, the U.S. Centers for Disease Control and Prevention (CDC) began tracking illnesses at the population (rather than individual) level using its multi-layered surveillance system for seasonal flu, which tracks hospitalizations, outpatient medical visits, and other measures.

2009 Influenza Pandemic Status as of September 10, 2009

International: World Health Organization (WHO):

(<http://www.who.int/csr/disease/swineflu/en/index.html>)

- WHO declared an influenza pandemic (Phase 6) on June 11. On July 11, WHO asked nations to suspend routine reporting of cases, and stopped publishing case counts, saying they did not accurately reflect pandemic status.
- WHO advises no restriction of regular travel or closure of borders; however, sick individuals are advised to delay travel. Officials report no infection risk from consumption of well-cooked pork products.

United States Government:

(<http://www.flu.gov/>; <http://www.cdc.gov/h1n1flu/>; <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>)

- A Public Health Emergency is in effect (under Section 319 of the Public Health Service Act).
- CDC has released to states 11 million treatment courses of the antiviral drugs Tamiflu and Relenza.
- FDA has issued Emergency Use Authorizations for certain unapproved uses of Tamiflu and Relenza, for use of certain respirator masks, and for use of unapproved diagnostic tests for the H1N1 flu strain.
- CDC has issued guidances for the general public; for clinicians and laboratories; regarding pregnant women and other groups; regarding travel; regarding affected schools and communities; and others.
- The U.S. federal government and manufacturers are developing a pandemic vaccine and preparing for a vaccination campaign. HHS Secretary Sebelius has waived liability resulting from the use of these products, and enabled an injury compensation program. Priority groups have been identified to receive vaccine.
- Congress provided up to \$7.7 billion in emergency supplemental appropriations (P.L. 111-32).

The H1N1 pandemic flu strain is an apparent reassortment of several existing strains of influenza A subtype H1N1 virus, including strains typically found in pigs, birds, and humans (see box below). The CDC reports that the symptoms and transmission of the novel H1N1 flu from person to person are much like that of seasonal flu. Laboratory testing of the new strain indicates that the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) are generally effective in treating illnesses caused by the pandemic strain. In contrast to seasonal flu, the pandemic strain appears to cause serious illness more often among children, and less often among the elderly. However, like seasonal flu, pregnant women and individuals with serious chronic diseases appear to be at greater risk of serious illness from the pandemic strain.

In response to the outbreak in April, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), assumed the role of Principal Federal Official, coordinating federal response efforts. Charles E. Johnson, then the Acting Secretary of Health and Human Services (HHS), declared a public health emergency. Among other things, this allowed the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs), permitting certain unapproved uses of Tamiflu and Relenza (such as in very young children) and some types of protective facemasks, and the use of unapproved diagnostic tests for the new flu strain.

CDC released stocks of antiviral drugs, respiratory protection devices, and other medical supplies from the Strategic National Stockpile (SNS), to help states respond to the outbreak. CDC reported that it released to state health officials 11 million of the 50 million treatment courses of Tamiflu and Relenza stockpiled in the SNS, and purchased additional courses to replenish the stockpile. CDC also activated its Emergency Operations Center to coordinate the agency's response activities, and sent 400,000 treatment courses of antiviral drugs to Mexico. CDC's initial advice to travelers to postpone all non-essential travel to Mexico has been rescinded, and travelers are now urged to take appropriate precautions while traveling.

According to DHS, U.S. border control agents are visually inspecting incoming travelers, and following the standard procedure of referring those who appear to be sick to CDC quarantine stations or local health officials. Early in the outbreak, Administration officials resisted calls to implement more aggressive measures such as closing the U.S.-Mexico border, noting that the new flu strain was already in the United States and that the focus of mitigation strategies was on controlling the spread of infection in affected communities.

Many U.S. communities closed schools when students were found to be infected with the new flu strain. School closure decisions, made by local officials, were based on initial CDC guidance, which was revised as it became clear that the virus was in wide circulation, and that the illnesses it caused were generally mild. CDC now recommends against routine school closures when small numbers of students are infected, arguing that such closures may do little to reduce the spread of the virus, while placing a considerable burden on the affected community. This instance illustrates the challenges facing government officials as they attempt to make evidence-based decisions about community mitigation interventions in a constantly changing environment. (See "Pandemic Preparedness and Response in Schools.")

The U.S. response to the pandemic triggered a slate of plans that were developed, beginning around 2004, to address concerns about the global spread of another novel flu strain, the H5N1 avian flu. In FY2006 supplemental appropriations, Congress provided \$6.1 billion for pandemic planning across several departments and agencies. These earlier efforts, and others aimed at preparedness for bioterrorism and emerging infections in general, have generally streamlined the response to the H1N1 pandemic. (See "Appropriations and Funding.")

Influenza Defined

Influenza (“flu”) is a respiratory illness that can be transmitted from person to person. Flu viruses are of two main genetic types: Influenza A and B. Influenza A strains are further identified by two important surface proteins that are responsible for virulence: hemagglutinin (H) and neuraminidase (N).

Seasonal flu circulates each year in the winter in each hemisphere. The dominant flu strains in global circulation change from year to year, but most people have some immunity. Infection can be fatal, however. CDC estimates that there are about 36,000 deaths from seasonal flu each year, on average. Vaccines are made each year based on predictions of the strains that are most likely to circulate in the upcoming flu season.

Avian flu (“bird flu”) is caused by viruses that occur naturally among wild birds, and that may also affect domestic poultry. In 1997, a new H5N1 strain of avian flu emerged in Asia, and has since caused millions of deaths among domestic poultry, and hundreds of deaths in humans. Health officials have been concerned that this strain could cause a human pandemic, and governments around the world have carried out a number of preparedness activities, including vaccine development and stockpiling, and planning for continuity of services.

Swine flu occurs naturally among wild and domestic swine. People do not normally get swine flu, but each year CDC identifies a few isolated cases of human flu that are caused by flu strains typically associated with swine.

Pandemic flu is caused when a novel strain of human flu (i.e., one that spreads from person to person) emerges and causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease is often more severe than is typical of seasonal flu.

(Adapted from HHS, “Flu Terms Defined,” <http://www.pandemicflu.gov>. For more information about pandemic flu, see “Understanding Pandemic Influenza” in CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*.)

To address the current situation, the Obama Administration requested about \$9 billion in emergency supplemental appropriations and transfer authority. On June 26, the President signed P.L. 111-32, which provides \$1.9 billion in FY2009 supplemental appropriations immediately, and an additional \$5.8 billion contingent upon a presidential request documenting the need for additional funds. The President has twice requested portions of the contingent funding. (See “Emergency Supplemental Appropriations for FY2009.”)

Efforts to prepare for a voluntary mass vaccination campaign are underway. In June, HHS Secretary Kathleen Sebelius issued a declaration waiving liability and enabling a compensation program in the event that a pandemic vaccine is used, and injuries result. A CDC advisory committee has developed recommendations for groups that should be given priority in the event that vaccine becomes available in limited amounts. (See “Vaccine Development, Licensing, and Use.”)

In August, the President’s Council of Advisors on Science and Technology (PCAST) released a report assessing preparations for a possible resurgence of pandemic flu in the fall, and recommending additional actions. The report also laid out a “plausible scenario” for a fall resurgence that could result in 30% to 50% of the U.S. population being infected, with up to 1.8 million hospitalizations and 90,000 deaths. The Council warned of the possibility of considerable strain on the nation’s health system. (See “Government-wide Pandemic Preparedness and Response.”)

This report describes the WHO process to determine the phase of a threatened or emerging flu pandemic, and touches on several related issues. It then provides additional information about selected actions taken by DHS and HHS, and by state and local authorities; lists congressional hearings held to date; and provides information about appropriations and funding for pandemic flu preparedness and response activities. Finally, the report summarizes U.S. government pandemic flu planning documents, and lists sources for additional information about the situation.

All dates in this report refer to 2009 unless otherwise specified. This report will be continually updated to reflect unfolding events.

Key Official Actions by WHO

Determination of Influenza Pandemic Phase

The World Health Organization is the coordinating authority for health within the United Nations system. It is responsible for providing leadership, guiding a research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. WHO does not have enforcement powers.

An influenza pandemic occurs when a novel flu strain emerges and spreads across the globe, causing human illnesses. For that to happen, the virus must have the following features: it must be genetically novel so that there is a lack of preexisting immunity; it must be pathogenic (i.e., capable of causing illness in humans); and it must be easily transmitted from person to person.

WHO, in consultation with experts in member countries, monitors the spread of influenza among human populations, and has developed a scale to monitor pandemic risk. It consists of five “pre-pandemic” phases with increasing incidence of animal and then human illness and transmission, and a sixth phase that represents a full-blown human pandemic, with sustained viral transmission and outbreaks in most or all regions of the world. Historically, flu pandemics have occurred in multiple waves before subsiding. **Table 1** describes the phases of a flu pandemic, as defined by WHO.

As a result of the rapid spread of the new flu strain, WHO raised the pandemic alert level from Phase 3, where it had been for several years because of the threat of H5N1 avian flu, to Phase 4 on April 27, and then to Phase 5 on April 29.¹ Phase 3 meant that a novel flu strain was causing sporadic small clusters of human illness, but was not sufficiently transmissible to sustain community-level outbreaks. Phase 4, by contrast, signaled that human-to-human transmission of the new H1N1 virus was sufficient to sustain community-level outbreaks. According to WHO, raising the alert level to Phase 5 meant that there was sustained community-level transmission in two or more countries within one WHO region, and that a pandemic could be imminent. The pandemic phases are depicted in graphical form in **Figure 1**. The figure displays Phases 5 and 6 together, signifying that Phase 5 is a call for concerted global pandemic response efforts.

On June 11, WHO raised the level to Phase 6, declaring that an influenza pandemic, caused by the new H1N1 strain, was underway. According to WHO Director General Dr. Margaret Chan:

Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable.... The world is now at the start of the 2009 influenza pandemic. We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch. No previous pandemic has been detected so early

¹ WHO, “Pandemic (H1N1) 2009,” <http://www.who.int/csr/disease/swineflu/en/index.html>.

or watched so closely, in real-time, right at the very beginning. The world can now reap the benefits of investments, over the last five years, in pandemic preparedness.²

Table 1. WHO Influenza Pandemic Phases
(current alert level is highlighted)

Phase	Description
Phase 1	No animal influenza virus circulating among animals has been reported to cause infection in humans.
Phase 2	An animal influenza virus circulating in domesticated or wild animals is known to have caused infection in humans and is therefore considered a specific potential pandemic threat.
Phase 3	An animal or human-animal influenza reassortant ^a virus has caused sporadic cases of small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.
Phase 4	Human-to-human transmission of an animal or human-animal influenza reassortant ^a virus able to sustain community-level outbreaks has been verified.
Phase 5	The same identified virus has caused sustained community-level outbreaks in two or more countries in one WHO region. ^b
Phase 6	An influenza pandemic. In addition to the criteria defined in Phase 5, the same virus has caused sustained community-level outbreaks in at least one other country in another WHO region. ^b
Post-peak Period	Levels of pandemic influenza in most countries with adequate surveillance have dropped below peak levels.
Possible New Wave	Level of pandemic influenza activity in most countries with adequate surveillance rising again.
Post-pandemic Period	Levels of influenza activity have returned to the levels seen for seasonal influenza in most countries with adequate surveillance.

Source: Adapted by CRS from WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Table 1, p. 13, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

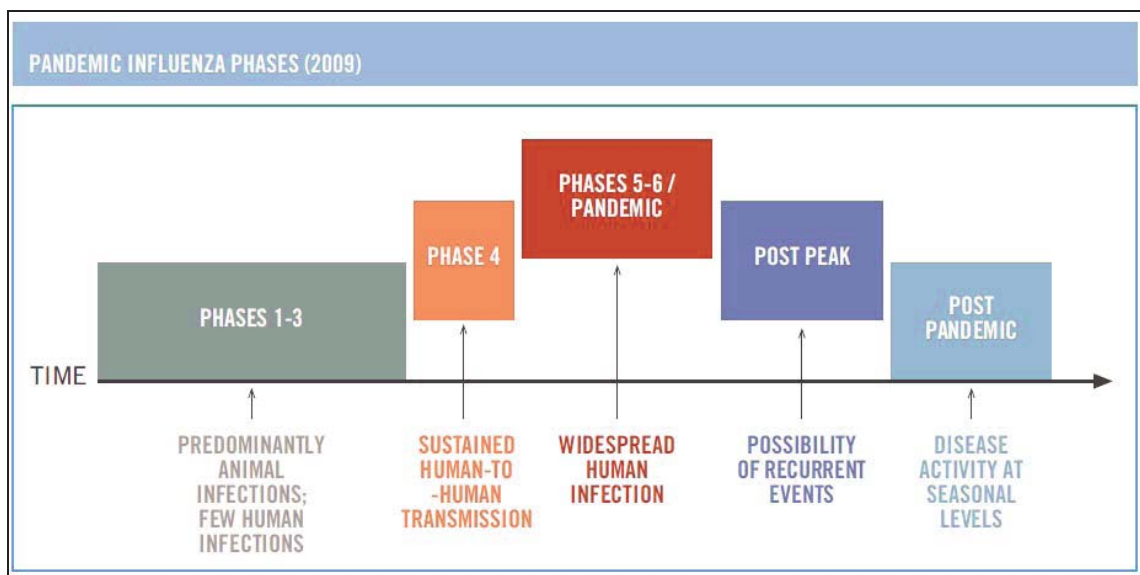
- a. A reassortant virus results from a genetic reassortment process in which genes from animal and human influenza viruses mix together to create a new strain.
- b. WHO governs through six regional offices that do not strictly correspond with the world's continents. The WHO regions are the African Region; the Region of the Americas; the South-East Asia Region; the European Region; the Eastern Mediterranean Region; and the Western Pacific Region. See "WHO—Its People and Offices," <http://www.who.int/about/structure/en/index.html>.

For several years, WHO urged governments, corporations, and other interests to develop pandemic influenza preparedness and response plans. Generally these plans are staged according to WHO pandemic phases. WHO has noted that under the current definitions, pandemic phases do not reflect the severity of illness, but rather the global extent of sustained community-level outbreaks. Some members of the public, however, have come to think of any flu pandemic as a catastrophic incident on the scale of the one that occurred in 1918, or that many feared could result from the deadly H5N1 avian flu if it became transmissible among humans. Some argued that the definition of a pandemic should be rewritten to take severity into account, and that a

² WHO, "World Now at the Start of 2009 Influenza Pandemic" (Statement of Dr. Margaret Chan), press release, June 12, 2009, <http://www.who.int/csr/disease/swineflu/en/index.html>.

Phase 6 pandemic designation for the current H1N1 flu situation could trigger over-reactions that were more disruptive than the disease.³

Figure 1. WHO Influenza Pandemic Phases



Source: WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Figure 3, p. 31, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

International Health Regulations

In 2005, the World Health Assembly adopted a revision of the International Health Regulations (IHR), giving a new mandate to WHO and member states to increase their respective roles and responsibilities for the protection of international public health. The IHR(2005) require signatory nations (which include the United States) to notify WHO of all events that may constitute a “Public Health Emergency of International Concern,” and to provide information regarding such events. The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and signatories to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.⁴

On April 25, 2009, upon the advice of the Emergency Committee called under the rules of the IHR(2005), the WHO Director-General declared the global threat of H1N1 flu a Public Health Emergency of International Concern. This designation calls upon signatories to provide timely and transparent notification of events to WHO, to collaborate with other countries in disease reporting and control, and to adopt effective risk communication strategies to reduce the potential

³ See, for example, Robert Roos, “WHO Drawing Closer to Declaring a Pandemic,” *CIDRAP News* (Center for Infectious Disease Research and Policy), June 2, 2009, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>.

⁴ For more information, see CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

for international disease spread and the likelihood of unilateral imposition of trade or travel restrictions by other countries.⁵

Travel Guidance

A number of governments have instituted enhanced passenger screening practices at their borders, and policymakers have debated more extensive prohibitions against the entry of travelers from countries or areas affected by the outbreak. The WHO has consistently advised against movement restrictions as a means to control influenza, citing a lack of evidence of their effectiveness, coupled with their potentially harmful effects on public confidence, local economies, and trade.⁶

Food Safety Guidance

WHO has published a joint statement with Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (known by its French acronym, OIE), and the World Trade Organization (WTO), saying:

In light of the spread of influenza A(H1N1), and the rising concerns about the possibility of this virus being found in pigs and the safety of pork and pork products, we stress that pork and pork products, handled in accordance with good hygienic practices recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, will not be a source of infection.

To date there is no evidence that the virus is transmitted by food. There is currently therefore no justification in the OIE Terrestrial Animal Health Standards Code for the imposition of trade measures on the importation of pigs or their products.⁷

Key U.S. Government Activities

Government-wide Pandemic Preparedness and Response

Under current law, the Secretary of Homeland Security leads all federal incident response activities, while the Secretary of HHS leads all federal public health and medical incident response activities under the overall leadership of the Secretary of Homeland Security.⁸ The Government Accountability Office (GAO) has noted, in the context of pandemic flu planning, that "... these federal leadership roles involve shared responsibilities between [HHS] and [DHS], and it is not clear how these would work in practice." GAO recommended that HHS and DHS

⁵ WHO, *International Health Regulations*, <http://www.who.int/ihr/en/>. See, also, Rebecca Katz, "Use of Revised International Health Regulations during Influenza A (H1N1) Epidemic," *Emerging Infectious Diseases*, vol. 15, no. 8 (August 2009), <http://www.cdc.gov/eid/content/15/8/1165.htm>.

⁶ WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

⁷ *Joint FAO, OIE, WHO and WTO Statement on A(H1N1) virus*, May 2, 2009, http://www.wto.org/english/news_e/news09_e/jt_stat_02may09_e.htm. See, also, CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 "Swine Flu"*: *Questions and Answers*, by Renée Johnson.

⁸ See CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

conduct training and exercises to ensure that federal leadership roles are clearly defined and understood. As recently as July 2009, GAO testified that although some recommended exercises had been undertaken, it was unclear whether they rigorously tested federal leadership roles in a pandemic.⁹

GAO also recommended, among other things, that federal pandemic plans published in 2006 be updated.¹⁰ DHS Deputy Secretary Jane Holl Lute recently testified that an implementation plan for response to the current pandemic is being finalized, under the leadership of the National Security Council.¹¹

In August, the President's Council of Advisors on Science and Technology (PCAST) released a report assessing preparations for a possible resurgence of H1N1 flu and recommending additional actions.¹² PCAST also noted the potential ambiguity in the leadership roles of DHS and HHS, and recommended that the Homeland Security Advisor¹³ be given primary responsibility for decision making during the pandemic response, saying:

The Working Group has some concerns, based on conversations with representatives of the various agencies involved, that decision-making authorities and processes may not be completely clear in all cases. Primary Federal responsibilities for response to an epidemic are lodged in two departments ([HHS] and DHS), with significant involvement of others (Education, Defense, State, Agriculture, Labor), and coordination by White House staff. While the National Strategy for Pandemic Influenza Implementation Plan provides a comprehensive list of assignments for a multitude of offices, agencies, and departments involved in the Federal planning process, the large number of tasks and responsible units tends to obscure the primary seat of responsibility.... The Working Group believes it would be valuable to clarify these matters before events accelerate in September and assign to the Homeland Security Advisor the responsibility for ensuring that all of the important decisions are made in a timely fashion and with appropriate consultation with the President.¹⁴

The PCAST report also laid out a “plausible scenario” for a fall resurgence that could result in 30% to 50% of the U.S. population being infected with H1N1 pandemic flu, with up to 1.8 million hospitalizations and 90,000 deaths.¹⁵ The Council warned of the possibility of considerable strain on the nation's health system. Although the Council made clear that these projections were provided for planning purposes and did not represent its prediction of a likely

⁹ See, for example, U.S. Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed*, GAO-09-909T, July 29, 2009, pp. 6-7, <http://www.gao.gov>.

¹⁰ Ibid.

¹¹ Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

¹² Executive Office of the President, President's Council of Advisors on Science and Technology, *Report to the President on U.S. Preparations for 2009-H1N1 Influenza*, August 7, 2009, press release and link to full report at http://www.whitehouse.gov/the_press_office/Presidents-Council-of-Advisors-on-Science-and-Technology-PCAST-releases-report-assessing-H1N1-preparations/ (hereafter referred to as PCAST report).

¹³ This designation presumably refers to John Brennan, who serves as Assistant to the President for Homeland Security and Counterterrorism. For more information on the organization of the Homeland Security Council and its staff under the Obama Administration, see The White House, Office of the Press Secretary, “Statement by the President on the White House Organization for Homeland Security and Counterterrorism,” press release, May 26, 2009, http://www.whitehouse.gov/briefing_room/PressReleases/.

¹⁴ Ibid, p. 32.

¹⁵ PCAST report, p. viii.

scenario, the report led to some alarm among readers, prompting Dr. Thomas Frieden, the CDC Director, to say that unless the behavior of the H1N1 virus changed, the situation was not expected to be as serious as the Council's scenario portrayed.¹⁶

Department of Homeland Security (DHS)

Leadership Designation

On April 27, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), stated in a press briefing that she was serving as the coordinator of the federal response to the flu outbreak, having assumed the role of Principal Federal Official (PFO).¹⁷ According to the National Response Framework (NRF), which guides a coordinated federal response to disasters and emergencies in general, the Secretary of Homeland Security leads federal incident response.¹⁸

Applicability of the Stafford Act

The Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) authorizes federal assistance to public and private not-for-profit entities affected by catastrophes, upon a presidential declaration. Two levels of declaration may be made, based on the scope and severity of an incident: a declaration of *emergency*, which provides a lower level of assistance, and a declaration of *major disaster*, which provides a higher level. The Stafford Act is administered by the Federal Emergency Management Agency (FEMA), which can draw from a Disaster Relief Fund to provide assistance for activities that are eligible under the Act.¹⁹

Major disaster declarations under the Stafford Act have historically involved common meteorological or geological disasters, wildfires, and terrorist acts such as bombings. The applicability of major disaster assistance to infectious disease threats—whether natural (e.g., a flu pandemic) or intentional (bioterrorism)—has been a matter of debate. Historically, major disaster assistance has been tailored to address disaster consequences such as the destruction of infrastructure or the displacement of victims, neither of which is a likely consequence of infectious disease outbreaks.

A legal analysis by CRS concluded that emergency assistance under the Stafford Act could be provided by the President in the event of a flu pandemic, but also noted that whether major disaster assistance would be authorized is not clear. There is no precedent for a major disaster declaration in response to an infectious disease threat. Furthermore, the legislative history of the Stafford Act suggests that this issue was not addressed by Congress when it drafted the current

¹⁶ “No Flu Vaccines Before Mid-October, CDC Predicts,” *Reuters*, August 26, 2009.

¹⁷ Department of Homeland Security, *Remarks by Secretary Napolitano at Media Briefing on H1N1 Flu Outbreak*, April 27, 2009, <http://www.dhs.gov/ynews/>.

¹⁸ CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by Bruce R. Lindsay. The PFO position has been controversial, however, because it may conflict with the role of the Federal Coordinating Officer (FCO), a leadership position established in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).

¹⁹ CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by Keith Bea; and CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

definition of a major disaster, and neither inclusion nor exclusion of flu pandemics from major disaster assistance is required as a matter of statutory construction.²⁰

In the *National Strategy for Pandemic Influenza: Implementation Plan*, the George W. Bush Administration assumed that the President's authority to declare a major disaster pursuant to the Stafford Act could be applied to a flu pandemic.²¹ In 2007, FEMA issued a Disaster Assistance Policy regarding Stafford Act assistance that may be provided during a flu pandemic, which includes costs associated with emergency medical care when provided by an eligible entity (generally, a public or non-profit private entity).²²

There has not, at this time, been a Stafford Act emergency or major disaster declaration in response to the H1N1 flu pandemic. In recent comments, DHS Secretary Janet Napolitano suggested that she did not plan to invoke the Stafford Act for the pandemic response.²³ However, DHS Deputy Secretary Jane Holl Lute recently testified that the Stafford Act may be invoked for the pandemic response under certain circumstances, and that DHS has planned accordingly.²⁴

Customs and Border Protection (CBP) Activities

When the novel H1N1 flu outbreak began in the United States, Customs and Border Protection (CBP), in DHS, reported monitoring incoming travelers at ports of entry (typically a visual inspection for possible symptoms), providing information about disease control measures, and referring symptomatic persons to a CDC quarantine station²⁵ or a local public health official for evaluation. According to DHS, "There are no border restrictions in effect. U.S. Customs and Border Protection continues to monitor the health status of incoming visitors at our land, sea and air ports watching out for illness as part of their standard operating procedure."²⁶

Administration officials resisted calls for more aggressive measures such as closing the U.S.-Mexico border. WHO and CDC officials commented that scientific evidence does not support closure of a border to travelers as an effective means of controlling the spread of influenza.²⁷ Also, as a matter of law, U.S. citizens cannot be barred from entering the United States, so any

²⁰ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

²¹ Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, Appendix C, "Authorities and References," p. 212.

²² FEMA, "Emergency Assistance for Human Influenza Pandemic," Disaster Assistance Policy 9523.17, March 31, 2007, at <http://www.fema.gov/pdf/government/grant/pa/policy.pdf>.

²³ Kevin Robillard, "Officials Say Swine Flu Vaccine is Coming," *CQ Homeland Security*, July 9, 2009. For more information, see CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

²⁴ Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

²⁵ CDC, "Quarantine Stations," http://www.cdc.gov/ncidod/dq/quarantine_stations.htm.

²⁶ DHS, "Department Response to H1N1 (Swine) Flu," July 24, 2009, <http://www.dhs.gov/files/programs/swine-flu.shtm>.

²⁷ Donald G. McNeil, "Containing Flu Is Not Feasible, Specialists Say," *The New York Times*, April 29, 2009. See also WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

border closure could only exclude aliens.²⁸ Finally, any such measures would likely be resource-intensive, involving considerable disruption of trade and other economic interests.²⁹

Department of Health and Human Services (HHS)

Determination of a Public Health Emergency

On April 26, Charles E. Johnson, then the Acting HHS Secretary, declared a public health emergency pursuant to Section 319 of the Public Health Service Act.³⁰ Among other things, this enabled FDA to implement an authority in the Federal Food, Drug, and Cosmetic Act (discussed below) allowing for the emergency use of unapproved medical treatments and tests, under specified conditions, if needed during an incident. The determination, which would have expired after 90 days, was renewed by HHS Secretary Kathleen Sebelius on July 24.³¹

FDA: Emergency Use Authorizations

If an emerging defense, national security, or public health threat is identified for which no licensed or approved medical product exists, the Federal Food, Drug and Cosmetic Act authorizes the FDA Commissioner, under certain conditions, to issue an Emergency Use Authorization (EUA) so that unapproved but potentially helpful countermeasures can be used to protect the public health.³² On April 27, pursuant to authority provided by the prior public health emergency determination, FDA issued EUAs to allow emergency use of (1) the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) for the treatment and prophylaxis of influenza; (2) disposable respirators for use by the general public; and (3) an unapproved diagnostic test for the new flu strain.³³ Although Tamiflu and Relenza are already approved for use in the United States, the EUA supported federal recommendations to use them in ways not explicitly approved on the product label, such as the use of the product in young children, or beyond a certain duration of a patient's symptoms.

The EUA authority may also be invoked in the future for pandemic flu vaccines if they are developed using approaches that are not used in currently licensed products, such as the

²⁸ See "Closing the Border" in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

²⁹ See "Port of Entry Policies and Procedures" in CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.

³⁰ HHS, "HHS Declares Public Health Emergency for Swine Flu," press release, April 26, 2009, <http://www.hhs.gov/news>. More information about this authority is available in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister, and CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

³¹ HHS, "Determination that a Public Health Emergency Exists," July 24, 2009, http://www.hhs.gov/secretary/phe_swh1n1.html.

³² Food and Drug Administration (FDA), *Guidance: Emergency Use Authorization of Medical Products*, July 2007, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>. See also FDA and CDC, online course on Emergency Use Authorization, 2009, <http://www.bt.cdc.gov/training/eua/index.html>.

³³ Information is available at FDA, "Emergency Use Authorizations Questions and Answers," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153297.htm>. Emergency use of a second unapproved test was authorized on July 24. FDA, "FDA Authorizes Emergency Use of Another Test for 2009 H1N1 Influenza Virus," press release, July 24, 2009, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>.

incorporation of adjuvants into the vaccine to enhance the immune response. (See the subsequent section “Vaccine Development, Licensing, and Use.”)

CDC: Travel Notices

On April 27, CDC issued a Travel Health Warning, its highest advisory level, recommending that U.S. travelers avoid all nonessential travel to Mexico.³⁴ On April 28, the Department of State issued a travel alert to U.S. citizens of the health risks of travel to Mexico due to the flu outbreak, noting the CDC’s Travel Health Warning of the previous day.³⁵ On May 15, CDC downgraded the Travel Health Warning for Mexico, and the Department of State lifted its travel alert. Travelers to Mexico are now advised to be alert regarding local conditions, practice good hygiene, and consult with their physicians regarding any health conditions that could put them at higher risk of illness.³⁶ Advisories regarding travelers leaving the United States are voluntary. CDC has also published a number of guidance documents for travelers and the travel industry, including information regarding passenger screening practices in other countries, and guidance for airline and cruise ship operators.³⁷

CDC: Disease Surveillance

Because illnesses with the novel H1N1 flu have generally been mild, health officials acknowledge that the disease may be substantially underreported. It is likely that for every infection that results in a health care encounter and a confirmed laboratory test, there are many mild infections for which individuals don’t seek care, and silent infections in which individuals may be infectious to others in the absence of symptoms. Health officials in many U.S. states and cities have stopped running confirmatory tests on every suspected case of H1N1 influenza, feeling that better use of epidemiology and laboratory resources can be made by monitoring disease spread to new areas, rather than repeatedly confirming its presence in an affected area.³⁸

To get a clearer picture of the spread of the pandemic in the United States, CDC began tracking the H1N1 outbreak using its multi-layered surveillance system for seasonal flu. The system showed that during the week ending August 29, 2009, there were higher levels of flu-like illness than is normal for this time of year, and almost all of the flu viruses reported that week were the pandemic strain. Widespread transmission and an increase in outpatient visits for influenza-like illness were reported in some states, especially those in the Southeast.³⁹

³⁴ CDC, “Travel Health Warning: Travel Warning: Swine Influenza and Severe Cases of Respiratory Illness in Mexico—Avoid Nonessential Travel to Mexico,” April 27, 2009.

³⁵ U.S. Department of State, “Travel Alert: Mexico - 2009-H1N1 Influenza,” April 28, 2009.

³⁶ CDC, “Travel Health Precaution: Travel Health Warning for Novel H1N1 Flu in Mexico Removed,” May 15, 2009, <http://wwwn.cdc.gov/travel/content/travel-health-precaution/novel-h1n1-flu-mexico.aspx>; and U.S. Department of State, Bureau of Consular Affairs, “Travel Alert: Mexico - 2009-H1N1 Influenza,” May 15, 2009, http://travel.state.gov/travel/cis_pa_tw/pa/pa_3028.html.

³⁷ CDC, “Novel H1N1 Flu and Travel,” <http://wwwn.cdc.gov/travel/content/novel-h1n1-flu.aspx>.

³⁸ This approach should not affect medical care. Clinicians are advised to provide care, including treatment with antiviral drugs, based on the severity of a patient’s symptoms, the presence of conditions that would place a patient at greater risk of severe infection, and other clinical considerations. It is not necessary that H1N1 flu be confirmed in order for appropriate treatment to be provided.

³⁹ Information in this section is drawn from CDC, “Novel Influenza A (H1N1) – Congressional Update,” Issue #13, May 13, 2009; CDC, “FluView: A Weekly Influenza Surveillance Report Prepared by the Influenza Division,” (continued...)

To track seasonal flu, CDC collects, compiles, and analyzes information from various sources year round, and publishes a weekly report from October through mid-May. This year, the surveillance system remained operational during the summer to track the pandemic. The system is a collaboration between CDC and state and local health departments, public health and private clinical laboratories, vital statistics offices, health care providers, clinics, and emergency departments. Information is collected from several different data sources, as follows:

- *Viral Surveillance:* About 80 U.S. WHO Collaborating Laboratories and 70 National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories across the country report the number of respiratory specimens tested and the number positive for flu virus. All state public health laboratories participate as WHO collaborating laboratories, along with some county public health laboratories and some large medical centers. Most NREVSS participants are hospital laboratories.
- *Outpatient Illness Surveillance:* Information on outpatient health care visits for influenza-like illness (ILI) is collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet).
- *Mortality Surveillance:* Rapid tracking of influenza-associated deaths is done through two systems: (1) The 122 Cities Mortality Reporting System. Each week, the vital statistics offices of 122 cities report the total number of death certificates received and the number of those for which pneumonia or influenza was listed as the underlying or contributing cause of death; (2) Surveillance for Influenza-associated Pediatric Mortality. Influenza-associated death in a child is a nationally notifiable condition. Laboratory-confirmed influenza-associated deaths in children are reported through the National Notifiable Disease Surveillance System.⁴⁰
- *Hospitalization Surveillance:* Two systems monitor hospitalizations with laboratory confirmed flu infections: (1) The Emerging Infections Program (EIP) Influenza Project conducts surveillance for laboratory-confirmed influenza-related hospitalizations in children and adults in 60 counties covering 12 metropolitan areas of 10 states.⁴¹ (2) The New Vaccine Surveillance Network (NVSN) provides estimates of laboratory-confirmed flu hospitalization rates for young children in three counties: Hamilton County, OH; Davidson County, TN; and Monroe County, NY.
- *Summary of the Geographic Spread of Influenza:* State health departments report to CDC each week regarding the estimated level of spread of flu activity in their states.

Vaccine Development, Licensing, and Use

Overview

Vaccination is considered the best preventive measure against influenza. But, because of continuous changes in the genes of flu viruses, vaccines must be “matched” to strains in

(...continued)

<http://www.cdc.gov/flu/weekly/>; and CDC, “2009 H1N1 Flu (Swine Flu),” <http://www.cdc.gov/h1n1flu/>.

⁴⁰ CDC, “National Notifiable Diseases Surveillance System,” <http://www.cdc.gov/ncphi/diss/nndss/nndsshis.htm>.

⁴¹ San Francisco CA, Denver CO, New Haven CT, Atlanta GA, Baltimore MD, Minneapolis/St. Paul MN, Albuquerque NM, Las Cruces, NM, Albany NY, Rochester NY, Portland OR, and Nashville TN.

circulation to provoke good immunity. Flu vaccine production is time-consuming and involves several steps. First, the virus strain must be adapted for mass-production and suitability for use in a vaccine. (The adapted virus is called a “seed” virus.) Next, the adapted virus must be grown in large amounts. All flu vaccines that are currently licensed for use in the United States contain adapted flu virus that is grown in chicken eggs. Next, small amounts of finished vaccine are produced for use in clinical trials. Finally, if trials demonstrate that the vaccine is safe and effective, then finished vaccine is mass produced.⁴² Production capacity is finite, so vaccine becomes available in batches. In a typical flu season, vaccine is produced and becomes available over a period of several months, typically from September through December of each year.

Adapting and growing the virus can take variable amounts of time, and different flu strains “behave” differently during this process. In the best case, all of the steps described above take at least four months. More typically, about six months is required. Therefore, since a vaccine cannot be produced for a flu pandemic until the pandemic flu strain emerges, a matched vaccine would not be available for initial pandemic response. Recent U.S. pandemic planning efforts have focused on (1) expanding domestic capacity to mass-produce flu vaccine in the near term; (2) developing approaches to speed up and “stretch” existing production capacity, such as through the use of *adjuvants*, vaccine additives that boost the immune response so that a lower virus dose is effective;⁴³ and (3) developing better approaches for flu vaccine production in the future. Although recent progress has been made to improve domestic production capacity, a vaccine for use in the United States against the H1N1 pandemic strain is being developed using the egg-based process, with its significant lag time.

Vaccine Development and Production

U.S. efforts to make an H1N1 pandemic vaccine are underway. Federal officials have said that there are three key decision points in developing and using pandemic vaccines: (1) to develop adapted “seed” viruses and a prototype vaccine(s), and to conduct clinical trials; (2) to purchase and mass-produce large amounts of a promising vaccine; and (3) to administer the vaccine widely, that is, to conduct a mass-vaccination campaign. These decision points are presented in a timeline of the U.S. pandemic flu vaccine strategy in **Figure 2**.

Federal officials have proceeded to procure enough H1N1 pandemic vaccine for a nationwide campaign, and predict that vaccine will begin to become available in the United States in mid-October. Unless problems arise, H1N1 pandemic vaccine would not contain adjuvants, it would be approved as an amendment to existing licenses for seasonal flu vaccine (the usual process for the approval of seasonal flu vaccines each year, rather than an emergency use authorization), and some preservative-free vaccine would be produced for use in children and pregnant women.⁴⁴

⁴² See, for example, the figure by Sanofi Pasteur (a flu vaccine manufacturer), “A(H1N1) Vaccine Production Process,” May 2009, <http://www.vaccineplace.com/docs/H1N1productionprocess.pdf>. For additional information about flu vaccine development and manufacturing, see Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines*, September 2008, <https://www.cbo.gov/ftpdocs/95xx/doc9573/09-15-PandemicFlu.pdf>.

⁴³ For more information about the use of adjuvants, including safety concerns and possible effects on the global supply of pandemic flu vaccine, see Declan Butler, “Regulators Face Tough Flu-jab Choices,” *Nature News*, July 21, 2009, <http://www.nature.com/news/2009/090721/full/460446a.html>.

⁴⁴ CDC, “CDC Novel H1N1 Vaccination Planning Q&A,” September 2, 2009, <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>. In the United States, flu vaccine is produced in multi-dose vials containing the preservative thimerosal, and in preservative-free single dose syringes. Thimerosal contains mercury. According to CDC, there is no convincing scientific evidence of harm caused by thimerosal in vaccines, but in 1999, the CDC, other (continued...)

Figure 2 also shows that there may be a second wave of heightened transmission of H1N1 flu in the United States in the fall, which could precede the peak of seasonal flu activity and the initial availability of pandemic vaccine. The figure also shows the overlap between the production of seasonal flu vaccine for the Northern Hemisphere and production of H1N1 pandemic vaccine.

On May 22, HHS Secretary Kathleen Sebelius announced that approximately \$1 billion in existing funds would be used for pandemic vaccine clinical trials and for commercial-scale production of pandemic vaccine ingredients.⁴⁵ Also in May 2009, HHS issued new orders on existing contracts with several manufacturers to produce a bulk supply of vaccine antigen and adjuvant and to produce investigational lots of H1N1 vaccine. Most of this would be stored in bulk, and a small amount would be prepared as vaccine for use in clinical trials to evaluate vaccine safety and the dosage required to raise protective immunity. These efforts are led by the HHS Biomedical Advanced Research and Development Authority (BARDA), in coordination with the National Institutes of Health (NIH), FDA, CDC, and other HHS agencies.⁴⁶

On July 13, Secretary Sebelius announced that HHS would commit an additional \$884 million to purchase additional supplies of pandemic vaccine antigen and adjuvant. The funds would be used to place additional orders for bulk H1N1 antigen and adjuvant on existing contracts with Sanofi Pasteur, MedImmune, GlaxoSmithKline, and Novartis.⁴⁷

The NIH is responsible for coordinating clinical trials to determine the safety, effectiveness, and optimum dosing for the vaccine. Based on information from initial trials, an NIH official reported in August that there were no “red flags” regarding the safety of the H1N1 vaccine.⁴⁸ (However, rare adverse events—i.e., side effects—would not necessarily manifest until a product was widely used.) Two federal advisory committees have recommended, based on these results, that companies begin to “fill and finish” some pandemic vaccine at the usual dosages for seasonal flu vaccine, before dosing information for the pandemic vaccine is available from subsequent clinical trials, in order to have some vaccine available before mid-October.⁴⁹

(...continued)

federal agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. As is the case for seasonal flu vaccine, a portion of the pandemic vaccine is being produced without preservatives, for use in children and pregnant women. CDC, “Mercury and Vaccines (Thimerosal),” <http://www.cdc.gov/vaccinesafety/updates/thimerosal.htm>.

⁴⁵ HHS, “HHS Takes Additional Steps Toward Development of Vaccine for the Novel Influenza A (H1N1),” press release, May 22, 2009, <http://www.hhs.gov/news/>.

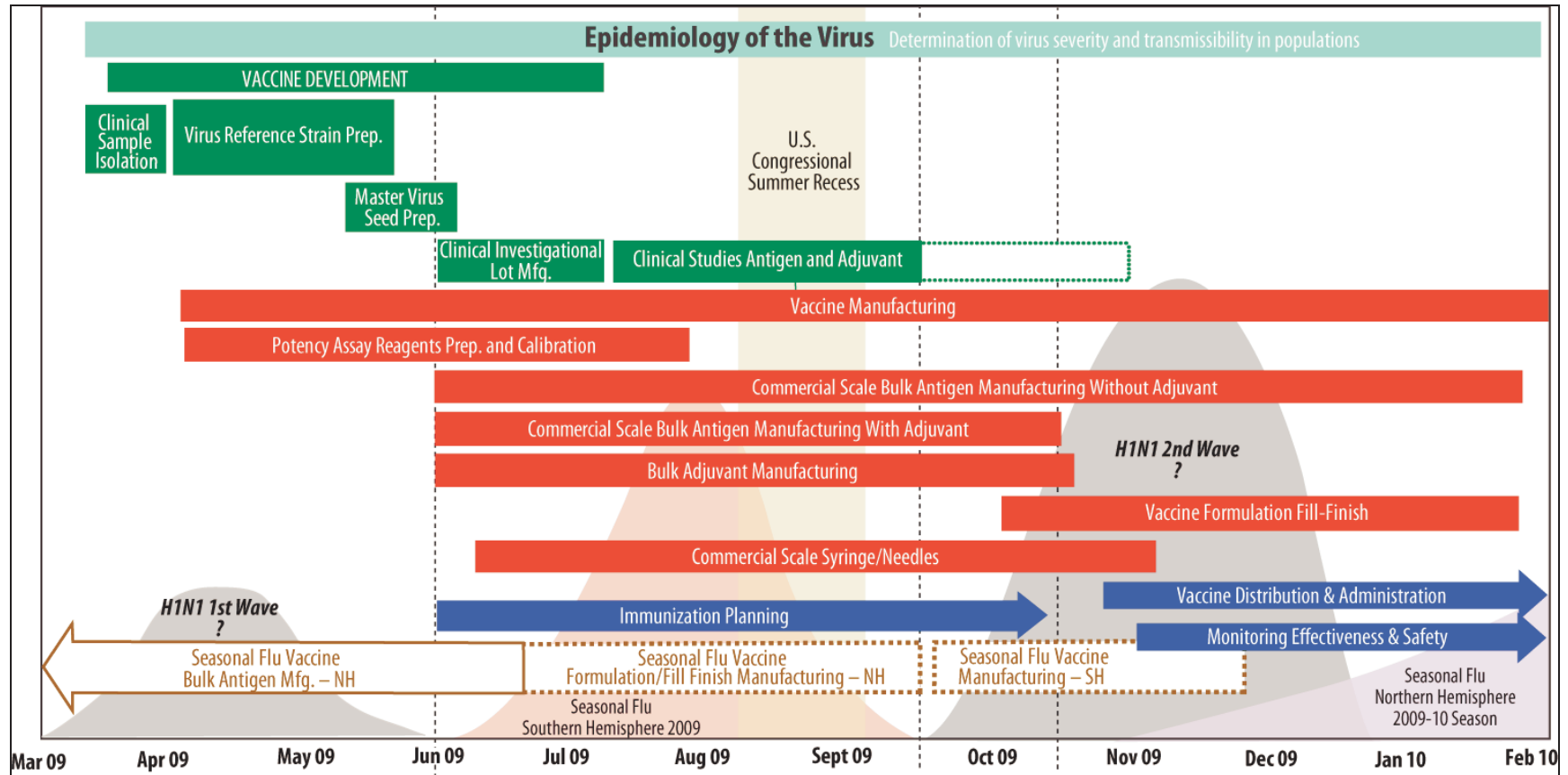
⁴⁶ HHS, Biomedical Advanced Research and Development Authority (BARDA), information regarding H1N1 vaccines, <http://www.hhs.gov/aspr/barda/index.html>.

⁴⁷ HHS, “HHS Purchases Additional H1N1 Vaccine Ingredients,” press release, July 13, 2009, <http://www.hhs.gov/news/>.

⁴⁸ Comments of Anthony Fauci, Director of the NIH National Institute for Allergy and Infectious Disease, transcript of CDC Joint Briefing with NIH and FDA on 2009 H1N1 Influenza, August 21, 2009, <http://www.cdc.gov/media/transcripts/2009/t090821.htm>.

⁴⁹ See transcript of the August 14, 2009 meeting of the National Biodefense Science Board, <http://www.hhs.gov/aspr/omsph/nbsb/>; and PCAST report, pp. 35-36.

Figure 2. Proposed Timeline for H1N1 Vaccine Development, Manufacturing, and Possible Distribution and Administration



Source: Adapted by CRS from background material provided for a meeting of the National Biodefense Science Board (administered by HHS) regarding the U.S. 2009 H1N1 vaccine strategy, May 22, 2009, <http://www.hhs.gov/aspr/conferences/nbsb/090522-nbsb-meeting.html>.

Vaccine Financing

Congress provided up to \$7.65 billion in FY2009 supplemental appropriations to HHS for the pandemic response, part of which is being used to support the purchase of vaccine and associated costs of planning and carrying out a nationwide vaccination campaign. (See the section “Emergency Supplemental Appropriations for FY2009.”)

Federal officials have said that all pandemic flu vaccine and necessary supplies—syringes, needles, sharps containers, and alcohol swabs—would be purchased by the federal government and made available to vaccinators at no cost.⁵⁰ According to CDC, a group representing many of the nation’s health insurers has said that its members would reimburse private health care providers for the costs of administering the vaccine to the insurers’ beneficiaries.⁵¹ In addition, the Centers for Medicare and Medicaid Services (CMS, an agency in HHS) reported that the Medicare program will reimburse providers for the costs of administration of multiple flu vaccines this fall and winter, including seasonal flu vaccine and recommended doses of H1N1 pandemic vaccine.⁵² State and local health agencies are also expected to conduct clinics at which vaccines would be provided at no charge to those who were vaccinated.

Vaccine Distribution

Federal officials are working with state and local health officials to implement a “blended” public- and private-sector distribution approach to a nationwide H1N1 pandemic vaccine campaign. During each flu season, much of the flu vaccine is purchased and delivered through private-sector distributors and providers. For the response to unanticipated threats such as bioterrorism, CDC maintains the Strategic National Stockpile (SNS) of drugs and medical supplies, and provides training and technical assistance to state and local health officials, who are responsible for distribution of stockpile materiel within their jurisdictions. Under the Vaccines for Children program, CDC distributes recommended pediatric vaccines (financed by the Medicaid program) to private providers for administration to eligible low-income children. The blended approach that is proposed for the pandemic vaccination campaign would use portions of each of these mechanisms to make vaccine available quickly to a variety of public- and private-sector providers and clinics.⁵³

⁵⁰ CDC, “Preparing for Vaccination with Novel H1N1 Vaccine,” July 31, 2009, <http://www.cdc.gov/h1n1flu/vaccination/provider/preparing.htm>; and “CDC Novel H1N1 Vaccination Planning Q&A,” July 24, 2009, <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

⁵¹ Ibid. Comments of America’s Health Insurance Plans (AHIP). See, also, <http://www.ahip.org/>.

⁵² CMS, “Medicare Fee-for-Service: Emergency and Disaster-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers,” Section 1—Urgent Preparedness Initiative: The H1N1 Influenza Pandemic, August 21, 2009, http://www.cms.hhs.gov/Emergency/Downloads/Medicare_FFS_Emergency_Qs_As_082609.pdf.

⁵³ CDC, “Preparing for Vaccination with Novel H1N1 Vaccine,” July 31, 2009, <http://www.cdc.gov/h1n1flu/vaccination/provider/preparing.htm>; and “CDC Novel H1N1 Vaccination Planning Q&A,” July 24, 2009, <http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm>.

Allocation to Priority Groups

Federal officials have said that a civilian pandemic flu vaccination campaign should be voluntary (i.e., individuals should not be compelled to be vaccinated).⁵⁴ Because pandemic vaccine would become available in phases, it is likely that early in a vaccination campaign, demand could exceed supply. Consequently, authorities have considered which groups should be given priority when supplies are limited. On July 29, the Advisory Committee on Immunization Practices (ACIP, which advises the CDC Director) recommended the following priority groups: (1) pregnant women, (2) people who live with or care for children younger than 6 months of age (who are too young to be vaccinated themselves), (3) health care and emergency services personnel, (4) persons between the ages of 6 months through 24 years of age, and (5) people from ages 25 through 64 years who are at higher risk because of chronic health disorders or compromised immune systems.⁵⁵ These recommendations are intended to protect groups that have been at risk of more serious illness from H1N1 flu infection up to this point, and to address sites of amplified transmission of infection. Health officials intend to monitor the spread and patterns of severity of illness, and may modify recommended priority schemes accordingly when vaccine becomes available. Also, although federal authorities provide guidance on vaccine allocation, final allocation decisions, and any enforcement of them, would be made at the state and local levels.⁵⁶

Adverse Event Monitoring

Assuming that there is a civilian vaccination program for H1N1 pandemic flu this fall, health officials plan to monitor for any possible adverse events (side effects) in persons who are vaccinated. At this time, officials plan to use the existing Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program co-sponsored by CDC and FDA, and other existing vaccine safety monitoring programs.⁵⁷ VAERS accepts reports from patients, providers, public health officials, and others through a website and toll-free number.⁵⁸

In 1976, a U.S. vaccination campaign was carried out for a pandemic flu threat that did not materialize (also called “Swine Flu”). However, evidence suggested that among those vaccinated, there was an increased risk of a serious and sometimes fatal neurologic side effect, a form of paralysis called Guillain-Barre Syndrome. The vaccination campaign was called off, and the credibility of public health officials was significantly compromised by the incident.⁵⁹

⁵⁴ CDC, “Questions and Answers: Novel H1N1 Influenza Vaccine,” August 3, 2009, http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm. See also CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman, and “Mandatory Vaccinations” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones

⁵⁵ CDC, “CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1,” press release, July 29, 2009, <http://www.cdc.gov/media/archives.htm>.

⁵⁶ For a discussion of applicable state activities during the seasonal flu vaccine shortage of 2004-2005, see “Vaccine Rationing” in CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by Sarah A. Lister and Erin D. Williams.

⁵⁷ CDC, “Influenza A (H1N1) 2009 Monovalent Vaccine Safety Monitoring: CDC Planning Recommendations for State, Local, Tribal, and Territorial Health Officials,” August 21, 2009, http://www.cdc.gov/h1n1flu/vaccination/safety_planning.htm.

⁵⁸ See <http://vaers.hhs.gov/contact.htm>.

⁵⁹ For more information, see Richard Neustadt and Harvey Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease* (U.S. Department of Health, Education, and Welfare, 1978), reprinted electronic edition at (continued...)

Liability and Compensation

On June 25, HHS Secretary Kathleen Sebelius issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act, Division C of P.L. 109-148) regarding the H1N1 pandemic vaccine.⁶⁰ The PREP Act waives liability and establishes an injury compensation program for the use of certain “covered countermeasures.” The June 25 declaration eliminates liability (with the exception of willful misconduct) for the United States, and for manufacturers, distributors, program planners, persons who prescribe, and employees of any of the above, who administer or dispense an H1N1 pandemic vaccine that qualifies as a “covered countermeasure” under conditions specified by the Secretary in the declaration.⁶¹ Under the law, claims under state law are preempted.

In addition, the declaration establishes a federal program to compensate individuals who are vaccinated for any injuries they may sustain, and authority for a fund to pay claims. The compensation program would be administered by the HHS Health Resources and Services Administration (HRSA), using the Smallpox Vaccine Injury Compensation Program as an administrative model.⁶² The fund, called the Covered Countermeasure Process Fund (CCPF), does not currently have a balance. However, in providing emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the CCPF.⁶³ On July 16, President Obama requested additional contingent funding under the new law, to be used for several activities, including funding for the CCPF.⁶⁴

Naming the Virus Strain

When news of the outbreak of a new flu strain emerged, WHO, CDC, and others referred to the virus as H1N1 “swine influenza” or “swine-origin influenza.” This is based on the presumed evolutionary origin of the strain from strains that circulate in swine, since it contains genetic material typically found in North American and Eurasian swine flu strains. There has been no clear evidence to date that pigs are involved in the transmission of this virus to humans, although there have been several instances of infection in swine herds believed to have resulted from contact with infected humans. There have been concerns that the term “swine flu” has had unwarranted economic and trade implications for swine and pork products, among other concerns.⁶⁵ Others have raised concerns that because of religious practices that call for the

(...continued)

<http://www.iom.edu/?id=65926>.

⁶⁰ Department of Health and Human Services, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

⁶¹ For more information, see CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows, and “The Public Readiness and Emergency Preparedness Act (PREP Act)” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

⁶² Health Resources and Services Administration, “Preparedness Countermeasures Injury Compensation,” <http://www.hrsa.gov/countermeasurescomp/default.htm>.

⁶³ H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

⁶⁴ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009, http://www.whitehouse.gov/the_press_office/Letter-from-the-President-regarding-H1N1/.

⁶⁵ CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”: Questions and Answers*, by Renée Johnson.

avoidance of swine and pork products by some persons of Jewish or Muslim faiths, disease control measures may be compromised in these groups if illness is perceived as a social stigma. On April 29, 2009, officials from HHS, DHS, and other federal agencies referred to the virus as “2009 H1N1” or “H1N1 flu.” On April 30, 2009, WHO began referring to the new strain as influenza A(H1N1).

Key State and Local Activities

State Pandemic Preparedness and Response

Since FY2002, all states have received HHS funds to prepare their public health and health care systems for public health threats and emergencies.⁶⁶ Beginning with FY2004, states were required, as a condition of these funds, to develop plans specifically for the response to a flu pandemic. Subsequently, Congress provided \$600 million in FY2006 emergency supplemental appropriations for states to continue their pandemic planning efforts.⁶⁷ When the H1N1 flu outbreak emerged, Congress provided an additional \$350 million in FY2009 emergency supplemental appropriations for state pandemic response.⁶⁸ (See the subsequent section “Emergency Supplemental Appropriations for FY2009.”)

Based on an analysis of state pandemic flu plans available as of July 2006, CRS found the plans to be more robust in their discussion of core public health activities such as disease surveillance and laboratory activities, and less robust in aspects of multi-sector preparedness, such as leadership designation, incident management, certain aspects of health care surge planning, and continuity planning for essential services such as food distribution.⁶⁹

In January 2009, HHS and DHS published *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council* (state assessment report), the findings of their comprehensive joint assessment of state pandemic planning through 2008.⁷⁰ This assessment echoed the findings of CRS, saying that preparedness was most advanced with respect to objectives that are exclusively or primarily the responsibility of state public health agencies, namely infectious disease surveillance and clinical laboratory operations; distribution of antiviral drugs and vaccines; mass vaccination; and public communications. In contrast, the assessment found that states were having difficulty planning for surges in health care and emergency medical services, and were especially having difficulty planning for continuity of non-health services, such as continuity of state agency operations; coordination of military support to civil authorities; law enforcement continuity; and ensuring the safety of the food supply.

⁶⁶ Funds are provided to the 50 states, DC, the territories, New York City, Chicago, and Los Angeles County.

⁶⁷ For more information, see the Appendix in CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale; and CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

⁶⁸ Award amounts are available at HHS, “States Eligible to Receive \$350 Million for H1N1, Seasonal Flu Preparedness Efforts,” press release, July 10, 2009, <http://www.hhs.gov/news/>.

⁶⁹ CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

⁷⁰ HHS and DHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January, 2009, <http://www.pandemicflu.gov/plan/states/index.html>. (Hereafter state assessment report)

Thus far, dedicated federal funding to state and local governments for pandemic preparedness has been provided only through HHS grants. Noting the challenges states face in assuring preparedness in non-health sectors, the state assessment report comments, “The [U.S. Government] has provided guidance and technical assistance for many of these activities but generally has not been in a position to award funds to help States develop them in the context of pandemic influenza preparedness.”⁷¹

If the pandemic continues to unfold as it has, and a fall wave produces generally mild to moderate illness, the pandemic’s effects on non-health sectors such as transportation and public utilities could be minimal. Based on the track record of the pandemic thus far, however, considerable challenges could persist for state and local officials responsible for the public health and health care sectors, and for schools (discussed in the next section).

Pandemic Preparedness and Response in Schools⁷²

When the H1N1 outbreak first began in the United States, many affected communities closed schools when students were found to be infected. Legal authority to close schools rests with state or local officials and is highly variable among the states. A CDC-requested study found that school closure is legally possible in most jurisdictions during both routine and emergency situations.⁷³ The study also indicated that state authority for closure may be vested at various levels of government and in different departments, generally the state or local education agencies or state or local departments of health.

In keeping with its obligation to provide public health assistance to states, on May 1, CDC, in consultation with the U.S. Department of Education, issued guidance with respect to school closures during the outbreak, recommending that “affected communities with laboratory-confirmed cases of influenza A H1N1 consider adopting school dismissal and childcare closure measures, including closing for up to 14 days depending on the extent and severity of illness.”⁷⁴ The guidance for this particular outbreak was derived from earlier broad guidance for pandemic planners, issued by CDC in 2007.⁷⁵

School closures are challenging for all parties involved. Among other things, parents must find alternate arrangements for care of their children, educators must adopt alternate means of delivering their services, and children’s education may be compromised. On May 5, CDC officials reissued their guidance regarding school closures. Noting that the disease appeared to be

⁷¹ State assessment report, p. 43.

⁷² For more information, see “School Closures” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones, and CDC, “Guidance for Child Care Programs, Schools, Colleges and Universities,” <http://www.cdc.gov/h1n1flu/guidance/>.

⁷³ James G. Hodge, Jr., Dhruvajyoti Bhattacharya, and Jennifer Gray, “Legal Preparedness for School Closures in Response to Pandemic Influenza and Other Emergencies,” <http://www.pandemicflu.gov/plan/school/schoolclosures.pdf>.

⁷⁴ CDC, “Change in CDC’s School and Childcare Closure Guidance,” press release, May 5, 2009, <http://www.cdc.gov/media/>. See, also, U.S. Department of Education, “H1N1 Flu Information,” <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>.

⁷⁵ CDC, *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States - Early Targeted Layered use of Non-Pharmaceutical Interventions*, Appendix 6, Pandemic Influenza Community Mitigation Interim Planning Guide for Elementary and Secondary Schools, February 2007, pp. 87-91, <http://www.pandemicflu.gov/plan/community/index.html>.

widespread and generally mild, CDC said that under the circumstances, widespread school closures may be more burdensome than beneficial to affected communities. The revised guidance recommended against closures based on individual cases of H1N1 flu. It recommended instead that emphasis be placed on keeping sick students and employees home, and that closings be considered if the burdens of infection and absenteeism were substantial.⁷⁶

As with CDC guidance in general, recommendations regarding school closure are intended to be weighed by local officials in light of local circumstances. In the original guidance, as quoted above, CDC recommended that state and local officials “consider adopting school dismissal and childcare closure measures, including closing for up to 14 days depending on the extent and severity of illness.”⁷⁷ Although this language placed considerable discretion in local hands, local officials may initially have been reluctant to scale back from immediate 14-day closures when the virus was detected. In addition to initial uncertainty about the outbreak’s severity, there may also have been uncertainty about local decision-making protocols. In an assessment of state pandemic flu preparedness conducted by HHS and DHS in 2007 through 2008, planning for student dismissal and school closure was found to be a weakness among the states. More than half of them were graded as having either “many major gaps” or “inadequate preparedness” for this planning task.⁷⁸

Outbreaks in schools largely subsided over the summer. Outbreaks emerged at summer camps, however, posing additional challenges for residential camps in providing care for ill campers. CDC has developed infection control guidance for day and residential camps; and for colleges and universities.⁷⁹ Transmission of the H1N1 virus is evident in a number of elementary and secondary schools and colleges and universities as students return for the fall. For example, the American College Health Association has begun tracking voluntary reports of pandemic flu activity at colleges and universities, and received reports of cases at schools in most states during the last week of August. In particular, cases were reported from schools in every one of the states in the Southeast.⁸⁰

Congressional Hearings

Congressional committees in both chambers have convened or planned hearings to assess the emergence of the new strain of H1N1 influenza. Hearings are listed below.

⁷⁶ CDC, “Update on School (K–12) and Child Care Programs: Interim CDC Guidance in Response to Human Infections with the Novel Influenza A (H1N1) Virus,” May 5, 2009 (continually updated), http://www.cdc.gov/h1n1flu/K12_dismissal.htm.

⁷⁷ CDC, “Change in CDC’s School and Childcare Closure Guidance,” press release, May 5, 2009, <http://www.cdc.gov/media/>.

⁷⁸ HHS and DHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, “Operating Objective B.4—Enhance State Plans to Enable Community Mitigation through Student Dismissal and School Closure,” January 2009, pp. 25-26, http://www.pandemicflu.gov/plan/states/state_assessment.html.

⁷⁹ CDC, “H1N1 Flu Clinical and Public Health Guidance,” <http://www.cdc.gov/h1n1flu/guidance/>.

⁸⁰ American College Health Association, “Pandemic Influenza Surveillance: Influenza Like Illness (ILI) in Colleges and Universities,” http://www.acha.org/ILI_Surveillance.cfm.

Senate

Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *The Public Health Response to the Swine Flu Epidemic*, April 28, 2009.

Committee on Health, Education, Labor, and Pensions, *The Swine Flu Epidemic: The Public Health and Medical Response*, April 29, 2009.

Committee on Homeland Security and Governmental Affairs, *Swine Flu: Coordinating the Federal Response*, April 29, 2009.

Appropriations Agriculture, Rural Development, and FDA Subcommittee, *Hearing to Discuss the 2009 H1N1 Virus*, May 7, 2009.

Homeland Security and Governmental Affairs, Subcommittee on State, Local and Private Sector Preparedness and Integration, *Pandemic Flu: Closing the Gaps*, June 3, 2009.

Homeland Security and Governmental Affairs, Subcommittee on Oversight of Government Management, the Federal Workforce and the District of Columbia, *Pandemic Flu Preparedness and the Federal Workforce*, June 16, 2009.

House

Committee on Energy and Commerce, Subcommittee on Health, *Swine Flu Outbreak and the U.S. Federal Response*, April 30, 2009.

Committee on Foreign Affairs, Subcommittee on Africa and Global Health, *Global Health Emergencies Hit Home: The Swine Flu Outbreak*, May 6, 2009.

Committee on Education and Labor, *Ensuring Preparedness Against the Flu Virus at School and Work*, May 7, 2009.

Committee on Oversight and Government Reform, Subcommittee on the Federal Workforce, Postal Service, and the District of Columbia, *Protecting the Protectors: An Assessment of Front-Line Federal Workers in Response to the H1N1 Flu*, May 14, 2009.

Committee on Oversight and Government Reform, *State and Local Pandemic Preparedness*, May 20, 2009.

Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, July 29, 2009.

Small Business Committee, *The Challenges of the 2009-H1N1 Influenza and its Potential Impact on Small Businesses and Healthcare Providers*, September 9, 2009.

Appropriations and Funding

Public Health Emergency Funding Mechanisms

The Secretary of HHS does not have a dedicated source of funds to support the response to public health emergencies such as the current flu pandemic. Funds available to HHS from prior year appropriations for pandemic flu could support vaccine development and modest procurements, but would not have been adequate for procurements and related activities sufficient to support, for example, a mass-vaccination campaign, if one were needed. GAO has noted that the *National Strategy for Pandemic Influenza: Implementation Plan* (2006), which lays out 324 action items for federal agencies to prepare for and respond to a flu pandemic, contains no discussion of the possible costs of these actions, or how they would be financed.⁸¹

Upon the determination of a public health emergency pursuant to Section 319 of the Public Health Service Act, the Secretary of HHS may access a no-year Public Health Emergency Fund. Such a determination was made with respect to the H1N1 flu outbreak on April 26. (See the earlier section “Determination of a Public Health Emergency.”)⁸² The fund has not received a recent appropriation and does not have a balance, however, so the Secretary is not currently able to use this funding mechanism for the pandemic response.

There has not been a Stafford Act declaration for the current flu pandemic, so disaster relief funds administered by the Federal Emergency Management Agency (FEMA) are not available for response efforts. Many relevant activities may not be eligible for Stafford funds, even if they were available.⁸³ (See the earlier section, “Applicability of the Stafford Act.”)

The Secretary has authority to use a Covered Countermeasure Process Fund to compensate individuals for harm that results from their use of medical countermeasures, as identified in a declaration issued by the HHS Secretary.⁸⁴ A declaration was issued for the use of the antiviral drugs Tamiflu and Relenza for a possible pandemic flu virus in October 2008.⁸⁵ As noted earlier, a declaration was issued for the use of an H1N1 pandemic vaccine in June, 2009.⁸⁶ Compensation could be provided for serious physical injuries or deaths resulting from the use of these products

⁸¹ U.S. Government Accountability Office, *Influenza Pandemic: Continued Focus on the Nation’s Planning and Preparedness Efforts Remains Essential*, GAO-09-760T, June 3, 2009, pp. 10-11, <http://www.gao.gov>. See also Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, <http://www.pandemicflu.gov/plan/federal/pandemic-influenza-implementation.pdf>.

⁸² For more information, see “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

⁸³ See “Federal Statutory Authorities for Disaster Response” and “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister. See also CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

⁸⁴ CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows. The compensation program is administered by the Health Resources and Services Administration (HRSA) in HHS.

⁸⁵ HHS, “Declaration Under the Public Readiness and Emergency Preparedness Act” (notice regarding use of Tamiflu and Relenza), 73 *Federal Register* 61861-61864, October 17, 2008.

⁸⁶ HHS, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

in this situation, including for unapproved uses pursuant to an Emergency Use Authorization. (See “FDA: Emergency Use Authorizations.”) The Covered Countermeasure Process Fund does not currently have a balance. However, in providing FY2009 emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the Fund, and President Obama has sought to use contingent funds provided under the law for this purpose.⁸⁷

Emergency Supplemental Appropriations for FY2009⁸⁸

On April 27, Representative Obey, the Chairman of the House Appropriations Committee, and Senator Harkin, the Chairman of the Senate Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, both suggested that Congress might add funds to the pending FY2009 defense supplemental appropriation to respond to the H1N1 flu outbreak. On April 30, President Obama sent a letter to House Speaker Nancy Pelosi formally requesting \$1.5 billion for this purpose. Later, as the outbreak spread around the world, the President increased the request to almost \$9 billion in appropriations and contingent transfer authorities.⁸⁹

On June 26, the President signed P.L. 111-32, which provides \$1.9 billion in FY2009 supplemental appropriations immediately, and an additional \$5.8 billion contingent upon a Presidential request documenting the need for, and proposed use of, the additional funds. Amounts provided are as follows:⁹⁰

- As proposed by the House, \$1.85 billion is provided to HHS for the Public Health and Social Services Emergency Fund, to be available until expended, including not less than \$200 million to CDC for several specified activities, and not less than \$350 million for state and local public health response capacity.
- As proposed by the House, of the \$1.3 billion to HHS that is not specifically designated, the Secretary may transfer funds to other HHS accounts and to other federal agencies. All such transfers require notification to the House and Senate Appropriations Committees. Transfers to other federal agencies also require consultation with the OMB Director.
- As proposed by the House, of the \$1.3 billion to HHS that is not specifically designated, funds may be used for purchases for the Strategic National Stockpile (SNS), for construction or renovation of privately owned vaccine production facilities, and for the Covered Countermeasure Process Fund (CCPF).
- An additional contingent emergency appropriation of \$5.8 billion to HHS for the Public Health and Social Services Emergency Fund would become available for obligation 15 days after the President provided a detailed written request to

⁸⁷ H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

⁸⁸ Information in this section is tracked in greater detail in CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

⁸⁹ Ibid. The President requested \$2 billion in appropriations and almost \$7 billion additional in transfer authority from existing accounts. The request was not fully funded. Also, funds were provided as new appropriations, rather than transfers from existing accounts.

⁹⁰ H.Rept. 111-151, pp. 27-28, 34-35, 110, 114-116, 125-126, and 142.

Congress to obligate specific amounts for specific purposes, and only if needed to address the emergency. If such requirements were met, funds could generally be made available and transferred as per the \$1.3 billion in non-contingent funds provided as above, including for purchases for the SNS and the CCPF. However, authority to use these contingent funds for construction or renovation of privately owned vaccine production facilities is not provided.

- As proposed by the House, the Secretary of HHS is to continue monthly reporting of funds obligated and actions taken using funds designated for pandemic flu preparedness; and, in collaboration with the CDC Director, is to report within 90 days regarding the CDC's initial response to the outbreak in Mexico and the United States.
- To support global efforts to control the spread of the outbreak, \$50 million is provided to the President for the Global Health and Child Survival account.
- The conference report provided that if WHO were to announce that the current outbreak had progressed to a flu pandemic (i.e., Phase 6),⁹¹ and upon the President's determination and notification to Congress, available funds in four accounts from prior appropriations acts for the Department of State, Foreign Operations, and Related Programs—Global Health and Child Survival; Development Assistance; Economic Support Fund; and Millennium Challenge Corporation—may be used for pandemic response activities. If this authority is used, OMB is directed to replenish any funds reprogrammed from these accounts.

On July 16, President Obama requested \$1.825 billion of the contingent appropriation, to be used for procurement of vaccine adjuvant, immunization campaign planning, FDA regulatory activities, and funding for the CCPF.⁹²

On September 2, the President requested an additional \$2.716 billion of the contingent appropriation, to be used for the Departments of Agriculture, Defense, HHS, State, and Veterans Affairs to support the procurement of vaccine product and supplies, antiviral medications, preparations for a vaccination campaign, and agency preparedness activities.⁹³

Prior Funding for Pandemic Flu Preparedness

In the fall of 2005, in the aftermath of Hurricane Katrina, and as H5N1 avian flu was spreading across several continents, Congress provided \$6.1 billion in FY2006 supplemental appropriations for pandemic planning across several federal departments and agencies.⁹⁴ Since then, annual funding has been provided to CDC, FDA, and for other activities in HHS to continue work on

⁹¹ WHO declared the situation to be a flu pandemic, Phase 6, on June 11.

⁹² The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009, http://www.whitehouse.gov/omb/budget_amendments/.

⁹³ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, September 2, 2009, http://www.whitehouse.gov/omb/budget_amendments/. At this time, the President has requested \$4.541 billion of the \$5.8 billion contingent appropriation, leaving a balance of \$1.259 billion that the President may request at a later date.

⁹⁴ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

vaccine development, stockpiling of countermeasures, and assistance to states. In total, from FY2004 through FY2009, HHS has received almost \$9 billion for pandemic flu preparedness.⁹⁵ (See **Table 2.**) The U.S. Departments of Agriculture and the Interior have also received annual funding to monitor avian flu in domestic poultry and wild birds, respectively. The U.S. Agency for International Development (USAID) has received funds to assist other countries in managing avian flu transmission to humans, and preparing for a possible pandemic.⁹⁶

In addition to amounts it specifically appropriates, Congress is also interested in how agencies budget for influenza within their existing activities. However, defining such amounts is difficult, for two reasons. First, for many years, domestic public health capacity for infectious disease control has moved away from “categorical” funding and programs (i.e., one disease at a time), and toward the development of flexible capacity that can adapt to new, unanticipated threats. These flexible surveillance systems, laboratory networks, communications platforms, and other capabilities can pivot rapidly to address new threats. But because pandemic planning efforts are tightly woven into the fabric of these flexible capabilities, it is not easy to tease out threads that describe the nation’s investment solely for pandemic flu preparedness. Attempt to do so requires making judgments about what is “in” and “out” of scope that are somewhat arbitrary.

Second, for similar reasons, it can be difficult to tease apart investments made for pandemic flu, versus seasonal flu, versus avian or swine flu, versus investments in drug and vaccine development in general. Because different agencies use different methods and assumptions to account for their influenza spending, these amounts are not necessarily comparable between agencies, and caution is advised in adding such amounts together as if they were comparable.

HHS has tracked its pandemic influenza funding for the past several fiscal years, using comparable criteria from year to year. These amounts are presented in the department’s annual budget requests, in sections designated for pandemic influenza, and are presented in **Table 2.**

Table 2. HHS Funding for Pandemic Influenza, FY2004-FY2010

(dollars in millions, rounded)

Agency/Activity	FY2004	FY2005	FY2006 ^a	FY2007	FY2008	FY2009 regular ^b	FY2009 supp. ^c	FY2010 req.
OS and/or PHSSSEF	50	99	5,152	0	75	585	1,850	354
CDC	0	0	400	70	155	156	0	156
FDA	0	0	20	33	35	39	0	39
NIH	0	0	18	35	34	35	0	35
TOTAL, Program Level	50	99	5,590^d	138	299	815	1,850^c	584

Source: Compiled by Congressional Research Service from HHS annual “Budget in Brief” documents at <http://www.hhs.gov/asrt/ob/docbudget/>, unless otherwise noted below.

⁹⁵ This amount is exclusive of any funds that may be provided through contingent transfer authority as provided in FY2009 supplemental appropriations, discussed in the previous section of this report.

⁹⁶ Information can be found in CRS Reports on the applicable appropriations bills, at http://apps.crs.gov/cli/level_2.aspx?PRDS_CLI_ITEM_ID=73, and: CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2010*, by Tiaji Salaam-Blyther.

Notes: OS is Office of the HHS Secretary. PHSSEF is Public Health and Social Services Emergency Fund, an account administered by the Secretary, which Congress has typically used to provide one-time funding for non-routine activities. NIH is the National Institutes of Health.

- a. Appropriated in P.L. 109-148, the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, and P.L. 109-234, the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006. Funds are available until expended.
- b. Appropriated in P.L. 111-8, the Omnibus Appropriations Act, 2009. Pandemic flu funding was not included in P.L. 111-5, the American Recovery and Reinvestment Act of 2009 (ARRA).
- c. Appropriated in P.L. 111-32, the Supplemental Appropriations Act, 2009. The Act also provided the Secretary of HHS with an additional \$5.8 billion, contingent upon presidential request and demonstration of need. For more information, see CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein. On July 16, President Obama requested \$1.825 billion of the contingent appropriation. On September 2, President Obama requested an additional \$2.716 billion of the contingent appropriation.
- d. Total does not include \$30 million in supplemental funding to HHS that was transferred to the U.S. Agency for International Development (USAID).

U.S. Pandemic Influenza Preparedness Documents

In the George W. Bush Administration, pandemic flu preparedness efforts were coordinated by the Homeland Security Council.⁹⁷ Numerous federal and other documents that are specific to preparedness and response for a flu pandemic have been published. Selected documents are listed below. These plans are intended to address a pandemic caused by any so-designated flu strain, but they were written when there was significant global concern about H5N1 avian flu. To date, that flu strain has behaved quite differently from the H1N1 pandemic strain. In particular, the H5N1 strain has not shown the ability to transmit efficiently from person to person, but human infections that result directly from contact with infected poultry have generally been very severe, and there has been a high fatality rate.⁹⁸

Unless otherwise noted, the U.S. pandemic flu plans below can be found on a government-wide pandemic flu website managed by HHS.⁹⁹

- *The National Strategy for Pandemic Influenza*, November 2005, published by the Homeland Security Council, outlines general responsibilities of individuals, industry, state and local governments, and the federal government in preparing for and responding to a pandemic.
- *National Strategy for Pandemic Influenza, Implementation Plan*, May 2006, published by the Homeland Security Council, assigns more than 300 preparedness

⁹⁷ Incident preparedness and response are different functions. At each level of government, they involve different leadership roles, legal authorities, organizational structures, and funding mechanisms. Generally, during an incident, certain conditions must be met before a jurisdiction can implement response activities, or access funds reserved for that purpose. With respect to the current H1N1 flu outbreak, the U.S. federal government has commenced pandemic flu response activities, under the overall coordination of the Secretary of Homeland Security.

⁹⁸ For more information about H5N1 avian flu and related public health concerns, see WHO, *Avian influenza*, http://www.who.int/csr/disease/avian_influenza/en/index.html; WHO, *Confirmed Human Cases of Avian Influenza A(H5N1)*, http://www.who.int/csr/disease/avian_influenza/country/en/; and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister (archived).

⁹⁹ See <http://www.pandemicflu.gov/plan/federal/index.html>.

and response tasks to departments and agencies across the federal government; includes measures of progress and timelines for implementation; provides initial guidance for state, local, and tribal entities, businesses, schools and universities, communities, and non-governmental organizations on the development of institutional plans; provides initial preparedness guidance for individuals and families. One- and two-year implementation status reports have also been published.

- The *HHS Pandemic Influenza Plan*, November 2005, provides guidance to national, state and local policy makers and health departments, outlining key roles and responsibilities during a pandemic and specifying preparedness needs and opportunities. This plan emphasizes specific preparedness efforts in the public health and health care sectors.
- The *HHS Pandemic Influenza Implementation Plan, Part I*, November 2006, discusses department-wide activities: disease surveillance; public health interventions; medical response; vaccines, antiviral drugs, diagnostic tests, and personal protective equipment (PPE); communications; and state and local preparedness.
- *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early Targeted Layered use of Non-Pharmaceutical Interventions*, February 2007, published by CDC, guidance for “social distancing” strategies to reduce contact between people, with respect to: closing schools; canceling public gatherings; planning for liberal work leave policies; teleworking strategies; voluntary isolation of cases; and voluntary quarantine of household contacts.
- *Department of Defense Implementation Plan for Pandemic Influenza*, August 2006, provides policy and guidance for the following priorities: (1) force health protection and readiness; (2) the continuity of essential functions and services; (3) Defense support to civil authorities (i.e., federal, state, and local governments); (4) effective communications; and (5) support to international partners.
- *VA Pandemic Influenza Plan*, March 2006, provides policy and instructions for Department of Veterans Affairs (VA) in protecting its staff and the veterans it serves, maintaining operations, cooperating with other organizations, and communicating with stakeholders.
- *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, published by DHS, September 2006, provides business planners with guidance to assure continuity during a pandemic for facilities comprising critical infrastructure sectors (e.g., energy and telecommunications) and key resources (e.g., dams and nuclear power plants).
- *State pandemic plans*: All states were required to develop and submit specific plans for pandemic flu preparedness, as a requirement of grants provided by HHS.¹⁰⁰

¹⁰⁰ For more information, see HHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January 2009, at <http://www.pandemicflu.gov/plan/states/index.html>, and CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

Key Information Sources

CRS Reports and Experts

2009 H1N1 “Swine Flu”: CRS Experts: <http://www.crs.gov/experts/WE04022.shtml>

Current CRS Reports on public health and emergency preparedness in general:
http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3276&from=3&fromId=13

Current CRS Reports on specific aspects of the pandemic influenza threat:

- CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.
- CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.
- CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”*: *Questions and Answers*, by Renée Johnson.
- CRS Report R40588, *The 2009 Influenza Pandemic: U.S. Responses to Global Human Cases*, by Tiaji Salaam-Blyther.
- CRS Report R40619, *The Role of the Department of Defense During A Flu Pandemic*, by Lawrence Kapp and Don J. Jansen.
- CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.
- CRS Report RL32724, *Mexico-U.S. Relations: Issues for Congress*, by Mark P. Sullivan and June S. Beittel.
- CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?* by Edward C. Liu.
- CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.
- CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.
- CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by Frank Gottron.
- CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro.
- CRS Report RL31873, *Banking and Financial Infrastructure Continuity: Pandemic Flu, Terrorism, and Other Challenges*, by N. Eric Weiss.
- CRS Report RS22264, *Federal Employees: Human Resources Management Flexibilities in Emergency Situations*, by Barbara L. Schwemle.

Archived CRS Reports on the threat of pandemic influenza: These products generally discuss concerns about a possible human flu pandemic resulting from H5N1 avian influenza, and enhanced federal preparedness efforts during 2005 through 2007.

- CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.
- CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther.
- CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

World Health Organization (WHO) Information

- Information about the current H1N1 pandemic flu situation: <http://www.who.int/csr/disease/swineflu/en/index.html>
- Pandemic Influenza Preparedness and Response: A WHO Guidance Document, (April 2009): <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>
- Current phase of flu pandemic alert: http://www.who.int/csr/disease/avian_influenza/phase/en/index.html
- Pan American Health Organization (PAHO), a regional office of the WHO, H1N1 flu page: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=805&Itemid=569
- International Health Regulations (2005): http://www.who.int/topics/international_health_regulations/en/

U.S. Federal Government Information

- Government-wide information: <http://www.flu.gov/>
- DHS, “Department Response to H1N1 (Swine) Flu,” with links to information in other federal departments and agencies: <http://www.dhs.gov/xprepresp/programs/swine-flu.shtm>
- CDC, H1N1 (swine flu) page: <http://www.cdc.gov/h1n1flu/>
- CDC Public Health Law Program, 2009 H1N1 Flu Legal Preparedness, <http://www2a.cdc.gov/phlp/H1N1flu.asp>
- FDA, 2009 H1N1 (Swine) Flu Virus, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>
- U.S. Department of Education, H1N1 Flu Information, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>
- Department of Defense Pandemic Influenza Watchboard: <http://fhp.osd.mil/aiWatchboard/>
- HHS Pandemic Planning Updates, addressing monitoring and surveillance, vaccines, antiviral medications, state and local preparedness, and communications, through

January 2009: <http://www.pandemicflu.gov/plan/federal/index.html#hhs> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)

Additional Information

- Canada: Public Health Agency of Canada: http://www.phac-aspc.gc.ca/alert-alerte/swine_200904-eng.php; Canadian Food Inspection Agency: <http://www.inspection.gc.ca/english/anim/disemala/swigri/swigrie.shtml>
- Security and Prosperity Partnership of North America, *North American Plan for Avian and Pandemic Influenza*, August 2007, [http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/\\$FILE/pandemic-influenza.pdf](http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/$FILE/pandemic-influenza.pdf)
- Center for Infectious Disease Research and Policy (CIDRAP), at the University of Minnesota, frequent updates, including scientific and technical information, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>

Author Contact Information

Sarah A. Lister
Specialist in Public Health and Epidemiology
slister@crs.loc.gov, 7-7320

C. Stephen Redhead
Specialist in Health Policy
credhead@crs.loc.gov, 7-2261